II. REMARKS

A. Status of the Claims

Claims 6, 24, 35 and 37 have been amended without prejudice or admission to recite that a coating derived from an aqueous dispersion of a hydrophobic polymer is "a controlled-release coating." Support for this amendment can be found throughout the specification. Claim 6 has been further amended to recite features of claims 25 and 42. Claim 24 has been further amended to recite features of claims 26 and 43.

Claims 25, 26, 42 and 43 have been cancelled without prejudice or admission.

Claims 6-8, 13-16, 24 and 27-41 are now pending.

It is respectfully submitted that no new matter has been added by virtue of the present amendments.

B. Double Patenting

Claims 6-8, 13 and 24-38 were rejected under judicially created doctrine of obviousness-type double patenting over claims 1-19 of the grandparent case (U.S. Patent No. 5,958,459).

Claims 6-8, 13 and 24-38 were rejected under judicially created doctrine of obviousness-type double patenting over claims 1-13 of the parent case (U.S. Patent No. 6,143,322).

Applicants acknowledge the double patenting rejections and submit that filing of the terminal disclaimers will be considered upon indication that claims are otherwise allowable.

C. Claim rejection under 35 U.S.C. §103

Claims 6-8, 13-16 and 24-43 have been rejected under 35 U.S.C. §103(a) over Goldie et al. (U.S. 4,844,909) in view of Oshlack et al. (U.S. Patent No. 5,286,493). The Examiner stated that "it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the coating and curing process as taught by Oshlack in the process of formulating the controlled release oral dosage formulation comprising hydromorphone for the method of treating pain as taught by Goldie et al." *Office Action, page 8.*

The rejection is respectfully traversed.

In an effort to advance prosecution and further differentiate from the cited references, independent claims 6 and 24 has been amended to recite that the dosage forms used in the methods of these claims have "been stabilized by curing for about 24 hours ... **and** at a relative humidity from about 60% to about 100%." Independent claim 37 already recites that the curing is "at a relative humidity from about 60% to about 100%."

The Oshlack patent (which has been relied on for the teaching of curing) does not describe a curing "at a relative humidity from about 60% to about 100%." To the contrary, it states that "it is **not necessary** to subject the coated substrate to humidity level above ambient conditions during the curing step in order to achieve a stabilized end product." *See column 8, lines 57-61 (emphasis added).* The Examiner has acknowledged on page 7 of the Office Action that "Goldie et al. ... fail to disclose a coating that has been stabilized by curing for about 24 hours or more at a temperature greater than the glass transition temperature of the hydrophobic polymer and at a relative humidity from about 60 to 100%."

Furthermore, it is respectfully submitted that the skilled person would not have been motivated to cure the formulations of the Goldie reference as described in the Oshlack patent because the "instability" problem described in the Oshlack patent is with the coatings derived

from **aqueous** dispersions of acrylic polymers (Cf. the Oshlack patent, column 2, lines 40-41, reciting that the "instability problem does not exist when the polymers are applied from organic solvent solution"), and the formulations of Goldie do not comprise such coatings.

The curing step recited in independent claims 6, 24 and 37 is **not** therefore described or suggested by the Oshlack patent and the Goldie reference.

The combination of the cited references also does not teach or suggest the specific release profiles recited in independent claims 6, 24, 35 and 37 (e.g., combinations of (i) the specific mean C_{max}, (ii) specific mean T_{max} and (iii) a duration of therapeutic effect for 24 hours). In response to the Examiner's statement on page 5 of the Office Action that "the limitations regarding "a dissolution profile ..." as well as C_{max} and C_{24} values are inherent when the same composition is cited by the prior art at the same dosage," it is respectfully submitted that the compositions of the Goldie reference are different from the presently claimed compositions for the reasons set forth in the response filed on December 12, 2008. The compositions of the Goldie reference cannot therefore inherently posses the features recited in these claims.

In response to the Examiner's statement on page 6 of the Office Action that "Goldie et al. teaches that dosage form achieving a peak plasma level between 2 and 4 hours are, surprisingly, interchangeable with dosage forms that achieve peak plasma levels between about 4 and 8 hours after administration," Applicants note that the Goldie reference does not make such an assertion. To the contrary, the Goldie reference differentiates a dosage form that provides a peak plasma level of hydromorphone between 2 and 4 hours from a dosage form providing a peak plasma level of hydromorphone at from about 4-8 hours, e.g., by stating that:

> ... it is usual in the pharmaceutical art to produce a formulation that gives a peak plasma level of the drug between about 4-8 hours ... The present inventors have surprisingly found that, in the case of hydromorphone, a peak plasma level at between 2-4 hours after administration gives at least 12 hours pain relief and, most surprisingly, that the pain relief obtained with such a formulation is greater than that achieved with formulations giving peak plasma

levels (of hydromorphone) in the normal period of 1-2 hours after administration."

See Column 2, lines 21-26.

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is specifically authorized to contact the undersigned by telephone in the event a telephone interview would advance the prosecution of the application.

Respectfully submitted,
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